

Orthopaedic cast system and components therefore

The invention relates to casting systems, to the components of casting systems, to processes for their preparation, to methods of use and to orthopaedic casts formed therefrom.

Casting bandages are normally used in the treatment of bone fractures or deformities to form a rigid or stiff immobilising or support orthopaedic cast on a body portion, such as a foot, leg, hand or arm. The use of a thin woven substrate, typically containing yarns of cellulosic, polyester, polyolefine or glass fibres or mixtures thereof, in the form of a strip or tube to which a hardenable resin is subsequently applied after the substrate has been applied to the body portion has been proposed. These bandage substrates are applied to a body portion for example by winding a strip or sliding a tubular substrate of the substrate over the affected portion and applying the resin which upon hardening forms a cast or by winding a strip of resin impregnated substrate around the body portion and allowing the resin to harden. However, in order to provide a cast of adequate strength, it has been found necessary in the past to apply several for example four to eight layers of the

Best Available Copy

thick and more aptly at least 4mm thick. The substrate will aptly be less than 8mm thick and more aptly be less than 6mm thick. The substrate can favourably be 3 to 8mm thick and can preferably be 4 to 6mm thick, for example about 5mm thick.

The system of the invention is normally extensible in at least the width direction and possibly also in the length direction thereof.

The casting system can suitably have an extension of at least 25%, more suitably at least 50%, favourably at least 75% and can preferably have an extension of at least 100% in the width direction. The extension of the tubular bandage can be measured by a conventional bandage extension test in which the tubular bandage in lay flat form is extended widthwise to its maximum extent. In this test the original (O_w) and stretched width (S_w) are recorded. The extension of the bandage can then be expressed as a percentage of the original width using the formula extension

$$\% = \frac{S_w - O_w}{O_w} \times 100$$

O_w

The extensible nature of the system allows it to be applied to and to conform to a body portion such as

crimped yarns or looped yarns for example "Terry" towelling and combinations of these knitting methods. The tubular knitted substrate however may advantageously contain holes or apertures in addition to the normal yarn interstices.

The yarns employed for the knitting process can comprise the so called 'high tenacity yarns' which although they can be readily knitted, have a resistance to deformation and thus an 'apparent resilience'. The tubular knitted substrate can comprise yarns of hydrophilic or hydrophobic fibres or a combination of these fibres. Suitable hydrophilic fibres include cellulosic fibres such as cotton, viscose or acetate rayon fibres. Suitable hydrophobic fibres include acrylic, polyester and polyolefine fibres such as high density polyethylene or polypropylene fibres. Other fibres such as polyamide fibres, however, may also be present in the bandage. Glass or carbon fibre may also be knitted up, for example by weft knitting to produce a suitable substrate.

Yarns suitable for use in the invention include polypropylene 420 denier/70 filament yarns such as those manufactured by Plasticizer Ltd, E-Glass fibres (50 Tex, 6 μ m filament) yarn sold by Pittsburgh Plate Glass Company and 110tex/200 filament Polyester yarn

'Fifties' or 'Best Available Copies' which are polyamide sheathed yarns containing respectively 50 and 75 rubber filaments per linear inch (2.54cm). The elastic yarn can be attached to or included in the tubular knitted substrate as a component which extends in circular or spiral manner around the circumference of the tube. Preferably the elastic yarn is included into the tube during the knitting process. Such knitting processes can be those conventionally used for making elastic tubular bandages or elastic stockings. Rubber filaments may be included, with advantage into glass fibre knitted substrates.

Other materials suitable for the tubular substrate include woven and non-woven materials such as lofted non-woven fabrics (having fibres randomly orientated in all three dimensions) and foam materials.

Substrates comprising hydrophilic fibres may also be pretreated with a water-proofing agent to inhibit the substrate absorbing moisture.

A tubular substrate for use in the invention which is to be used on the hand, wrist or lower arm may advantageously be coloured, for example patterned. Similarly, a tubular substrate for a bandage which is to be used on the foot, ankle or lower leg may

Best Available Copy
tertiary amine and/or a stabiliser such as an acidic material. Preferred catalysts are dimorpholino diethylether and bis(2,6-dimorpholino) diethylether. Preferred stabilisers are methane sulphonic acid and succinic anhydride.

Suitable water hardenable polyurethane prepolymer resins containing catalysts and/or stabilisers of this type are disclosed in International Patent Application No 86/01397, United States Patent No 4433680 and United Kingdom Patent No 2196944 the disclosure of which is incorporated herein by reference. Other resins suitable for use in the present invention include those described in International Publication No. WO89/08463 and in British Patent Specification No. 2207141.

The hardenable resin will normally be in a liquid state to facilitate the impregnation or coating process. Hardenable prepolymer resins for example polyurethane or acrylic prepolymer resins are preferably liquid at temperatures between 10° to 30°C. Solid or highly viscous prepolymers can be rendered liquid by any suitable method such as a hot melt or solvent method. The tubular substrate can be coated or impregnated with liquid prepolymer by conventional methods such as a two roll nip coating or impregnating method.

undercast padding.

Thus the casting system of the invention may include an outer layer comprising a tubular substrate carrying a hardenable resin and an inner layer comprising an undercast padding material.

A padding material such as the tubular padding material disclosed in European Patent Application No. 0356078 may be applied to the body portion prior to formation of the cast thereon (to render the cast comfortable on the body).

Alternatively the resin substrate and undercast padding may be formed as a composite.

According to a further embodiment of the present invention there is provided an orthopaedic casting system for application to a body portion comprising an elastically extensible composite tubular material having an outer layer of fabric carrying a hardenable resin and an inner layer of padding material.

Preferably the inner layer is a tubular layer.

The composite tubular material of the invention can be rendered elastically extensible by means of an

Best Available Copy

such as cellulose fibre for example cotton or viscose fibres can render the padding material moisture absorbent. Hydrophobic fibres however, can render the padding material relatively poorly water absorbent.

Favoured stockinette padding materials are tubular bulky stockinettes such as rib knitted or sliver knitted stockinettes or stockinettes containing crimped or looped yarns.

Preferably the tubular stockinette has an elastic component around its circumference such as an elastic yarn or thread to render the stockinette elastically extensible in the radial direction thereof.

Such a thread or yarn can form part of the stockinette that is a woven or knitted course or be attached to a surface of the stockinette. Favoured tubular stockinettes for use as a padding layer in the invention are those of the type conventionally used for elasticated tubular bandages such as those specified in the British Pharmacopedia (1988).

Such elasticated tubular stockinette comprise a knitted fabric of ribbed structure containing a covered natural or synthetic rubber elastic thread or yarn arranged in a spiral fashion in the tube. Typical

~~Such available hydrophobic fibres include polyester, polypropylene and high density polyethylene fibres.~~
Hydrophobic fibres can render the lofted non-woven fabric relatively non-absorbent so that any water penetrating the fabric can drain away.

The lofted non-woven fabric can also comprise meltable powder or fibres such as segmented, conjugate or bicomponent fibres of higher and lower melting points to bond the fibres in the fabric.

The lofted non-woven fabric use in the composite can suitably have a thickness of 2 to 10mm and preferably have a thickness of 3 to 8mm. Similarly the lofted non-woven fabric can suitably have a weight per unit area of 5 to 200g/m².

The lofted non-woven fabric will preferably be formed in a manner to render the fabric resilient.

An apt resilient lofted non-woven fabric for use in the invention which comprises hydrophilic fibres is known as SOFFBAN natural orthopaedic padding available from Smith & Nephew. Such a non-woven fabric comprises viscose rayon fibres, has a thickness of 3.6 to 4.2mm and a weight per unit area of 105 to 140g/m².

Suitable waterproofing agents include non-toxic waterproofing agents used for textiles such as wax, silicone resin or fluorinated polymer waterproofing agent. Such an agent are normally available as a solution or dispersion.

Apt waterproofing agents for polyester fibre non-woven fabrics are a wax waterproofing agents in emulsion form known as Nickwax TX10 available from Nickwax Ltd. and Super pel available from Grangers Ltd.

The non-woven fabric may be treated for example by impregnation to provide the waterproof agent throughout the thickness of the fabric. Alternatively the non-woven fabric may be treated, for example by coating, to provide the waterproof agent at a surface layer of the fabric.

Suitable water vapour permeable, water impervious layers for the non-woven fabric can comprise a water insoluble polymer which is preferably also an elastomer to render the layer elastic and conformable.

Such layers can be continuous, voided or microporous.

suitably Best Available Copy
and can preferably be 7 to 30g/m²
for example 10g/m².

Moisture vapour permeable lofted non-woven fabrics used in the invention can suitably have a moisture vapour transmission rate of at least 1000g/m²/24h, more suitably at least 2000g/m²/24h and preferably at least 5000g/m²/24h at 37°C at 100% to 10% relative humidity difference. The moisture vapour transmission rate of a non-woven fabric can be readily determined by the Payne Cup Method (in the upright position) described in European Patent No. 46071.

The lofted non-woven fabric may also comprise an elastically extensible material to render conformable to the body portion. Tubes formed from or comprising such a lofted non-woven fabric therefore can comprise an elastic component or components to provide this extensibility. Preferably elastic component or components are located around the circumference of the tube to render it elastically radially extensible or expandable in the radial direction thereof.

Suitable elastic components include elastic yarns, threads or strips conventionally used in elastic fabrics made of a natural or synthetic rubber for example polyurethane.

knitted Best Available Copy
at fabric or is attached to the outside of
these tubular fabrics or a tubular non-woven fabric.

The non-woven fabric used for the support layer may be a "two dimensional" non-woven fabric of the type used for cover layers on absorbent pads such as sanitary towels and diapers. Such non-woven fabrics advantageously have a soft feel to the skin. Tubes of these non-woven fabrics can be formed from a strip or sheet thereof in same manner as tube of lofted non-woven fabric as hereinbefore mentioned.

In the composite the non-elastic material or materials in the wall of the tube can be compressed into folds forming circumferential corrugations running parallel to the main axis of the tube thereby rendering the tube extensible or expandible in at least the radial direction. The wall of the tube will therefore usually exhibit substantially axial crepe, or crinkled or undulated fold pattern. Although the height of these folds will reduce as the tube is expanded example when it is being fitted over a body portion, the folds will reform and increase the thickness of the padding layer, and hence the cushioning effect of the layer when the tube is relaxed to conform with the body portion.

The lofted non-woven fabric layer can suitably be

intermediate layer may be retained by any of the methods hereinbefore described. During storage of the bandage the barrier layer prevents resin from contaminating the padding layer. However, upon immersion in water, the barrier layer is dissolved and water is permitted to enter the resin laden substrate from both sides. Preferably the inner layer is made of a hydrophobic material such that upon removal from the water bath, the padding material will rapidly dry out.

The casting system of the invention can be adapted in size to the size of the body portion to be immobilised by the cast formed by the composite. The elastically extensible nature of composite tubular material can be adapted to allow the bandage to be applied over a body extremity to the body portion and to conform therewith.

The composite construction of the inner and outer layers can be formed by bonding together or overlaying the padding and optionally any support layers forming the inner layer and the resin bearing substrate forming the outer layer. Bonding may be achieved by adhering the component layers using an adhesive as hereinbefore described or by stitching them together.

In alternative embodiment the resin may be

Best Available Copy
series of tubes, for example in the form of a continuous length of a tube from which individual tubes may be cut.

The system may be packaged within a pouch for example, where the resin is water activated a foil pack may be employed and which is impermeable to both liquid water and water vapour to inhibit premature hardening of the resin of the bandage. For light activated resins, the system may be packaged in an opaque pouch.

The system may be packaged as a flattened tube, and may have a suitable interliner to prevent adjacent portions of the inner surface of the tube from contacting each other. In an alternative arrangement the tube may be rolled up to form a "doughnut", preferably with an interliner separating adjacent surfaces of the rolled tube. Suitable interliners may be formed from wax-coated or siliconised papers and the like.

In order to assist application of the tubular system or unrolling of a prepackaged tubular system, slip agents may be incorporated into the resin or applied to the surface of the resin coated substrate. Suitable slip agents include silicones, surfactants and the like.

Best Available Copy

After the system has been applied to the body portion, the hardenable resin can be hardened, for example by actinic (ultra-violet or visible light) radiation or by contact with water or moisture to form a cast about the body portion. The system, however, can be contacted with water or with moisture vapour prior to application thereof providing that the system is in its prehardened flexible and extensible state during application.

The bandage system of the invention may conveniently applied to the body portion by means of an applicator.

Thus in another aspect the present invention provides in combination an applicator and a cast bandage system of the invention.

The applicator can be the conventional expandible cylindrical shaped applicator used for the application of tubular elastic bandages.

The composite tubular material of a hand or lower arm bandage system of the invention can conveniently be provided with a side hole towards one end thereof prior to or after application to accomodate a thumb region of

Best Available Copy

may be difficult to provide sufficient resin to immobilise the body portion without deteriorously effecting other properties such as breathability. In connection with this latter point it may be difficult in getting sufficient resin into the substrate, particularly in those cases where the resin hardens in contact with air.

Thus in a further aspect the invention provides an orthopaedic cast formed from the orthopaedic cast bandage system of the invention.

Such an orthopaedic cast is preferably formed on the body portion by spraying water or moisture onto a water hardenable resin carried on the fabric of the outer layer of the composite tubular material of the bandage of the invention. Such a method of formation avoids the necessity of immersing the body portion and the cast bandage system applied thereto into water.

A water hardenable orthopaedic cast, however, can be formed by contacting the hardenable resin on the outer layer of the bandage system with water or moisture before it is applied to the body portion, for example by immersing the bandage system and optionally an applicator therefor in water. The bandage system can then be applied over the body portion before the resin

Best Available Copy

resin it is desirable to dry the fabric for example by leaving it in vacuum, prior to coating or impregnation to reduce the water content thereof to not more than 1% by weight and preferably <0.1% weight.

When the inner padding layer of the composite tubular material comprises an elastically extensible lofted non-woven fabric such a layer can be formed by attaching the tubular non-woven fabric to an elastic component.

The elastic component however preferably forms part of an elastic extensible tubular inner support fabric. In which case the inner layer can be formed by attaching the lofted non-woven fabric to an inner support layer of tubular elastically extensible fabric.

In such a process the lofted non-woven fabric layer can be provided with axial folds such as undulating folds to render the layer extensible prior to, during or after it attached to inner support layer of tubular elastically extensible fabric.

Prior to attachment the lofted non-woven fabric can be embossed or compressed to provide the undulating folded layer. The undulating folds in the layer can also be provided by bonding, for example by adhesive or

around the best available copy the inner layer.

Preferably the outer surface of the inner support layer of tubular fabric containing or attached to the elastic component or components is provided with adhesive and the outer layer of lofted non-woven fabric strip or sheet is attached to inner layer by the adhesive. The adhesive can be provided prior of after expansion of the tubular fabric by any convenient coating method such as a solvent, hot melt or transfer coating method or by use of an adhesive coated strip component when forming the inner tubular fabric.

A preferred adhesive coating method for use in the process is a hot melt adhesive coating method using for example a spray or roller coating head. When such a method is employed during a process in which the tubular fabric is expanded widthwise in a flat form the hot melt adhesive will be coated on both outer surfaces of the flattened tubular fabric. The hot melt adhesive can advantageously be coated prior to expansion of the tubular fabric to inhibit penetration of the adhesive through the fabric such as stockinette fabric. In such a process the lofted non-woven fabric strip or sheet can be conveniently laminate to the adhesive coated surfaces of the expanded flat tubular fabric by passage through the nip of two pressure rollers. The rollers

Best Available Copy
present as a discontinuous layer.

Extending through the non-woven fabric layer are spirally wound elastic yarns 5.

An intermediate layer 6 of a resin impervious water-soluble material lies between the non-woven layer 4 and the outer layer 6.

The outer layer 6 is preferably a knitted substrate which carries a hardenable resin. Apertures 7 are provided in layer 6 to render the formed cast breathable.

Figure 2 illustrates one embodiment in which the layer 4 is compressed into corrugations which extend circumferentially around the inner support tubular layer 2. The layer 4 is bonded to the inner support layer 2 and the outer layer 6 by suitable adhesive 3, 3¹.

In Figure 3 the inner layer 2 extends beyond the end of the outer layer 6 and is wrapped around to form a cuff.

Referring to Figure 4, the casting system 1 is rolled up to form a torus with an interliner sheet 8.

vacuum oven at 60°C for 24 hours and then packed in a water-proof foil pack.

The polyurethane prepolymer resin used was that used in Example 2 of British Patent Specification No. 2207141.

The tube was impregnated with approximately 300g which is equivalent to a weight unit area of 5250g/m² of the polyurethane prepolymer resin.

The widthwise extension of the bandage and the thickness of bandage material were similar to that respectively of the original tube material.

The casting system was then packaged in an aluminium foil pouch to inhibit premature hardening for example contact with moisture.

Preparation of an Orthopaedic Cast of the Invention

A tubular padding material (length 34cm) similar to that disclosed in Example 3 of European Patent Application No 0356078 was applied to the wrist and lower arm of a volunteer. The casting bandage was removed from its pack, mounted on a conventional, tubular bandage applicator and immersed in water to

The substrate was knitted to a 1 x 1 Rib Net Pattern using a 6-inch Cylinder and Dial Knitting Machine with 180 needles for each of the cylinder and dial.

A polyamide sheathed rubber yarn (Heathcote 'Fifties') was inlaid every 8th course of the knitted fabric.

The lay flat width of the knitted substrate was 7.3cm and the wall thickness was about 3mm.

A length of the tubular substrate was impregnated with the same polyurethane prepolymer employed in Example 1 to a weight of 600g/m². The resin impregnated substrate was then cut into a 30cm length and sealed in an aluminium foil pouch.

Application of Cast

A length of elastic tubular stockinette (lay flat width 7.5cm) was placed onto a tubular bandage applicator and applied to the forearm and around the crooked elbow of a volunteer.

The resin impregnate substrate was removed from the pouch and rolled up to form a doughnut and immersed

The stockinette was a modified elasticated rib knitted tubular bandage (Tensogrip available from Smith & Nephew) containing cotton/viscose fibres and covered rubber threads spirally knitted into the fabric.

The outer surface of the stockinette was then sprayed with a thermoplastic polyurethane (Estane 5712 available from BF Goodrich) adhesive solution in methylene chloride and dried to give a weight per unit area of 13.3g/m². The coating was then covered with release paper and heated (temperature 125°C) under pressure to firmly anchor the polyurethane adhesive to the stockinette. A strip (of sufficient size) of lofted non-woven fabric (SOFFBAN SYNTHETIC) was heat laminated under pressure to cover the adhesive coated surface of the stockinette on both sides of the former by feeding the stockinette (on the former) and the non-woven fabric through the nip of two pressure rollers whilst heating the side of the former opposite to that at which the non-woven fabric is laminated. The tubular padding material so formed was then cut into 30cm lengths.

Antifoam MSA is an antifoam available from Dow Chemicals.

KL-26 is bis (2,6-dimethyl morpholino - N-ethyl) ether.

In the preparation the isonate 143L in a suitable container is heated to 63°C, the Voranol CP-260 and PPG 1025 added in that order and the mixture allowed to react for 90 mins at an exotherm raised temperature of 80°C. The reaction mixture was then cooled to 60-63°C and the isonate 240 added and allowed to react for 30mins. Antifoam MSA was then added and the reaction mixture cooled to 50°C. A vacuum was applied to the container and methane sulphonic acid and KL-26 added.

The polyurethane prepolymer resin had a viscosity of 20000 to 75000 centipoises at 25₁°C and a NCO content of >10%.

The stockinette was impregnated with weight unit area of 600g/m² of the polyurethane prepolymer resin. The tubular fabric resin material was cut into 24cm and 30cm lengths.

Preparation of a cast bandage of the invention.

The tubular padding material (length 30cm) was

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:**

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.